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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------------|---------------------|------------------|
| 09/522,336 | 03/09/2000 | Carlos Vonderwalde Freidberg | 24079-1080 | 3266 |

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EXAMINER

HO, UYEN T

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/522,336 | FREIDBERG ET AL. |
| | Examiner | Art Unit |
| | (Jackie) Tan-Uyen T. Ho | 3731 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 March 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-47 is/are pending in the application.

4a) Of the above claim(s) 29-47 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-28 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6.

4) Interview Summary (PTO-413) Paper No(s). _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other:

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 1/8/2002 and 3/12/2002 have been considered and placed in the application file.

Election/Restrictions

2. This application contains claims directed to the following patentably distinct species of the claimed invention: Species I: Figs. 1-7; Species II: Figs. 8-10; Species III: Figs. 11-13; Species IV: Figs. 14 and 16; Species V: Fig. 15.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. During a telephone conversation with Mr. Edward Lynch on 8/20/2002 a provisional election was made with traverse to prosecute the invention of Species I, claims 1-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-10, 13-15 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Chevillon et al. (6,248,116).

In regard to claims 1 and 15, Chevillon et al. disclose a stent comprising an expandable tubular body (105), at least one cover connector (361) on the tubular body (in the broadest interpretation, an element "on the tubular body" does not have to be integral or part of the tubular body). Wherein the connector (361) includes a first section adjacent a first end, a second section adjacent a second end and a third section between the first and second sections and the connector has an open configuration and a closed configuration in which the first and second section each has at least one bend so that the first and second section are bent together and are directed towards the third section (fig. 9).

In regard to claims 2-6, the connector has portions configured to bend when the connector assumes the closed configuration (fig. 9), wherein the connector assumes the closed configuration when the first and second sections each has a first bend (U-shape) in the same direction and a second bend toward the same direction (fig. 9).

In regard to claims 7-8, the first and second ends are tapered and pointed tip to pierce a stent cover (108).

In regard to claim 9, the tubular body (105) has a spaced apart wall sections defining an open-walled structure (fig. 1) and the connector (361) is secured to a support member (the strut of the tubular ring 105a) extending between the spaced apart wall sections (fig. 9).

In regard to claim 10, the support member (the strut of the tubular ring 105a) has first end and second ends secured to the tubular body (with the broadest interpretation, the strut secured together to form a tubular body at the curve between the struts, therefore, the first end and second of the strut will end at the beginning of the curve) and a third section of the connector is secured to the support member between the first and second ends of the support member (fig. 9).

In regard to claim 13-14, the connector (with its U-shape arms) is substantially perpendicular to the longitudinal axis of the tubular body in the open configuration (fig. 9). With the broadest interpretation, the connector is generally line parallel to the longitudinal axis of the tubular body in the open configuration.

In regard to claim 21, the cover (108) on the stent (105) extends from the first to the second end of the stent (fig. 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedberg (6,254,627) in view of Khosravi et al. (6,325,820) further in view of Chevillon et al. '116. Friedberg discloses a stent (12) and a biocompatible non-thrombogenic jacket or cover (14) covering the stent, wherein the jacket includes first and second ends and a first overlapping a second edge, suitable means for securing the jacket or cover on the stent, the jacket being about .005 mm to about .20 mm. Freidberg fails to disclose a cover connector, as claimed. Khosravi et al. teach securing a stent with a graft or an inner cover with staples or all the means (col. 4, lines 26-35) and Chevillon et al. disclose a staple attaching a stent and a cover, the staple including all the structure limitations of a cover connector, as claimed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ staples as disclosed by Chevillon et al. into Freidberg's stent and jacket such as staples have sizes to accommodate the thickness of the jacket of Freidberg in order to secure the jacket to the stent. Also, it would have been obvious matter of design choice to install the staples from the inside to the outside of the tubular body instead from the outside of the tubular to the inside of the tubular body, it would appear that the staples being installed either side would perform equally well securing the jacket on the stent and wherein so doing would make the third section of the cover connector adjacent to the inner or outer surface of the cover.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Winston et al. (6,117,166) disclose a stent, a cover covering the stent and means for securing the cover on the stent including staples.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

(Jackie) Tan-Uyen T. Ho
September 13, 2002



MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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